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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,511	06/30/2004	Stephen Francis Badylak	3220-72178	6418

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BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
03/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,511	BADYLAK ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 11-26-08 has been entered. Claims 11 and 19 have been amended. Claims 20 and 21 have been added. Claims 1-21 are pending. Claims 11-15 and 17-21 are under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 11-26-08 necessitates this new ground of rejection.

The phrase "wherein the DNA content of the liver basement membrane is 0.429 microgram of DNA or less per milligram of dry weight" in claims 20 and 21 is considered new matter. Applicants point out support for the phrase is on page 22, Example 8, of the specification. Example 8 of the specification shows DNA assay result of LBM treated with PAA (peracetic acid solution) with average 0.429 and standard deviation of 0.380. The value of 0.429 with standard deviation of 0.380 is in the range of 0.809 and 0.0049, which is different from 0.429 or less. Therefore, the specification fails to provide support for the phrase "wherein the DNA

content of the liver basement membrane is 0.429 microgram of DNA or less per milligram of dry weight". Thus, the phrase set forth above is considered new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al., 1980 (European Journal of Biochemistry/FEBS, Vol. 111, No. 2, pp. 485-490) in view of either Ollerenshaw et al., 2005 (US Patent No. 6,866,686 B2) or Wolfinbarger Jr. et al., 2004 (US Patent No. 6,734,018 B2). Applicants' amendment filed 11-26-08 necessitates this new ground of rejection.

Claims 19 and 21 are directed to a collagenous tissue graft structure comprising decellularized basement membrane wherein the basement membrane is substantially devoid of

DNA. Claim 21 specifies the DNA content of the basement membrane is 0.429 ug or DNA or less per mg of dry weight of the basement membrane.

Robinson teaches isolating basement membrane from rabbit kidney using detergent N-dodecyl sarcosine, the residual proteins were collagenous and the extracted membranes retained their continuity of structure and exhibited a matrix composed of fibrous and globular elements. The filtration properties of the membranes were studied in vitro and show an enhanced capacity to retain proteins (e.g. abstract).

Robinson does not specifically teach the basement membrane is substantially devoid of DNA or the DNA content is 0.429 ug/mg dry weight or less.

Ollerenshaw teaches a tissue graft produced by disinfecting a human or animal ureter tissue, decellularizing the disinfected tissue with an aqueous hypotonic buffer that lyses cells to form a tissue matrix and with nuclease to degrade nucleic acid associated with said tissue matrix, and washing said tissue matrix to remove cellular or extracellular debris to as to produce tissue graft (e.g. column 10, claim 1).

Wolfinbarger teaches a process for the production of commercializable quantities of acellular soft tissue grafts for implantation into mammalian system by removing the cellular populations, cellular remnants, nucleic acids, and small molecular weight proteins, lipids, and polysaccharides forming an acellular nonsoluble matrix. The acellular tissue can be implanted into a mammalian system (e.g. bridging column 2 and 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to prepare a tissue graft structure comprising decellularized basement membrane substantially devoid of DNA because Robinson teaches isolating basement membrane having

collagenous residual proteins and the extracted membranes retained their continuity of structure and exhibited a matrix, and both Ollerenshaw and Wolfinbarger teach preparation of acellular tissue graft by removing cellular populations, and removing nucleic acid or degrading nucleic acid. A basement membrane is a type of tissue graft and removing or degrading nucleic acid in a tissue graft would substantially devoid of DNA in the tissue graft and would be obvious to one of ordinary skill in the art. It also would be obvious to one of ordinary skill in the art to prepare a basement membrane having DNA content 0.429 ug/mg dry weight or less because both Ollerenshaw and Wolfinbarger teach removing nucleic acid or degrading nucleic acid from a tissue graft and the tissue graft would be substantially devoid of DNA, which would be close to zero and would be obviously less than 0.429 ug/mg dry weight of basement membrane.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to study filtration properties of the basement membranes in vitro as taught by Robinson or to implant the basement membrane into a mammalian system as taught by Wolfinbarger with reasonable expectation of success.

6. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al., 1980 (Advances in Experimental Medicine and Biology, Vol. 131, pp. 89-103) in view of either Ollerenshaw et al., 2005 (US Patent No. 6,866,686 B2) or Wolfinbarger Jr. et al., 2004 (US Patent No. 6,734,018 B2). Applicants' amendment filed 11-26-08 necessitates this new ground of rejection.

Claims 19 and 21 are directed to a collagenous tissue graft structure comprising decellularized basement membrane wherein the basement membrane is substantially devoid of

DNA. Claim 21 specifies the DNA content of the basement membrane is 0.429 ug or DNA or less per mg of dry weight of the basement membrane.

Brendel teaches isolation of vascular basement membrane from several organs, such as kidney, lung, placenta and brain, via nondisruptive detergent solubilization techniques with detergent and DNase (e.g. p. 89, Table 1). The vascular basement membrane is decellularized and the remaining materials include basement membrane, interstitial collagen and a few other proteins such as fibrin, tubulin and actin (e.g. p. 91, 1st paragraph).

Brendel does not specifically teach the basement membrane is substantially devoid of DNA or the DNA content is 0.429 ug/mg dry weight or less.

Ollerenshaw teaches a tissue graft produced by disinfecting a human or animal ureter tissue, decellularizing the disinfected tissue with an aqueous hypotonic buffer that lyses cells to form a tissue matrix and with nuclease to degrade nucleic acid associated with said tissue matrix, and washing said tissue matrix to remove cellular or extracellular debris to as to produce tissue graft (e.g. column 10, claim 1).

Wolfinbarger teaches a process for the production of commercializable quantities of acellular soft tissue grafts for implantation into mammalian system by removing the cellular populations, cellular remnants, nucleic acids, and small molecular weight proteins, lipids, and polysaccharides forming an acellular nonsoluble matrix. The acellular tissue can be implanted into a mammalian system (e.g. bridging column 2 and 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to prepare a tissue graft structure comprising decellularized basement membrane substantially devoid of DNA because Bredel teaches preparation of decellularized vascular

basement membranes from several organs, and both Ollerenshaw and Wolfinbarger teach preparation of acellular tissue graft by removing cellular populations, and removing nucleic acid or degrading nucleic acid. A basement membrane is a type of tissue graft and removing or degrading nucleic acid in a tissue graft would substantially devoid of DNA in the tissue graft and would be obvious to one of ordinary skill in the art. It also would be obvious to one of ordinary skill in the art to prepare a basement membrane having DNA content 0.429 ug/mg dry weight or less because both Ollerenshaw and Wolfinbarger teach removing nucleic acid or degrading nucleic acid from a tissue graft and the tissue graft would be substantially devoid of DNA, which would be close to zero and would be obviously less than 0.429 ug/mg dry weight of basement membrane.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to implant the basement membrane into a mammalian system as taught by Wolfinbarger with reasonable expectation of success.

7. Claims 11-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak, Stephen, 2002 (US Patent No. 6,379,710 B1, IDS-AG) in view of either Ollerenshaw et al., 2005 (US Patent No. 6,866,686 B2) or Wolfinbarger Jr. et al., 2004 (US Patent No. 6,734,018 B2). Applicants' amendment filed 11-26-08 necessitates this new ground of rejection.

Claims 11-15, 17, 18 and 20 are directed to a purified liver basement membrane graft composition comprising basement membrane of warm-blooded vertebrate liver tissue, wherein the purified liver basement membrane is substantially devoid of DNA, and wherein the liver basement membrane could be fluidized, in gel form, or in powder form, and a liver tissue derived

composition for supporting the growth of a cell population, said composition comprising said liver basement membrane composition and is devoid of source liver tissue endogenous cells, or said composition comprising culture-ware coated with a matrix comprising said liver basement membrane composition. Claims 19 and 21 are directed to a collagenous tissue graft structure comprising decellularized basement membrane wherein the basement membrane is substantially devoid of DNA. Claims 20 and 21 specify the DNA content of the basement membrane is 0.429 ug or DNA or less per mg of dry weight of the basement membrane.

Badylak teaches a tissue graft composition comprising liver basement membrane prepared by removing the cellular components from liver tissue by treating the liver tissue with a solution comprising an enzyme, such as trypsin or pepsin, and a calcium chelating agent or chaotropic agent such as a mild detergent Triton 100, or with a solution comprising only the chelating agent or chaotropic agent (e.g. abstract, column 3, lines 1-15). The liver tissue slice can be suspended in an agitated solution containing protease, optionally containing a chaotropic agent or a calcium chealating agent in an amount effective to optimize release and separation of cells from the basement membrane without substantial degradation of the membrane matrix (e.g. column 3, lines 16-24). Badylak further teaches that the liver basement membrane can be fluidized or in powder form (e.g. column 3, lines 39-60, column 11, 12), cell growth substrate are formed from fluidized forms of liver basement membrane and the fluidized tissue can be gelled to form solid or semi-solid matrix (e.g. column 8, lines 12-18), and the cell growth substrate can be combined with nutrients, such as minerals, amino acids, sugars, peptides, proteins, glycoproteins that facilitate cellular proliferation and growth factors (e.g. column 8, lines 26-32). Badylak also teaches that "fluidized forms of liver basement membrane can be used to coat

culture-ware with a matrix comprising liver basement membrane devoid of source liver tissue endogenous cells. Thus, liver basement membrane can be used as a cell growth substrate in a variety of forms, including a sheet-like configuration, as a gel matrix, as an additive for art-recognized cell/tissue culture media, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells" (e.g. column 7, lines 48-53).

Badylack does not specifically teach the basement membrane is substantially devoid of DNA or the DNA content is 0.429 ug/mg dry weight or less.

Ollerenshaw teaches a tissue graft produced by disinfecting a human or animal ureter tissue, decellularizing the disinfected tissue with an aqueous hypotonic buffer that lyses cells to form a tissue matrix and with nuclease to degrade nucleic acid associated with said tissue matrix, and washing said tissue matrix to remove cellular or extracellular debris to as to produce tissue graft (e.g. column 10, claim 1).

Wolfinbarger teaches a process for the production of commercializable quantities of acellular soft tissue grafts for implantation into mammalian system by removing the cellular populations, cellular remnants, nucleic acids, and small molecular weight proteins, lipids, and polysaccharides forming an acellular nonsoluble matrix. The acellular tissue can be implanted into a mammalian system (e.g. bridging column 2 and 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to prepare a tissue graft structure comprising decellularized basement membrane substantially devoid of DNA because Badylak teaches a tissue graft composition comprising liver basement membrane prepared by removing the cellular components from liver tissue, and

both Ollerenshaw and Wolfinbarger teach preparation of acellular tissue graft by removing cellular populations, and removing nucleic acid or degrading nucleic acid. A basement membrane is a type of tissue graft and removing or degrading nucleic acid in a tissue graft would substantially devoid of DNA in the tissue graft and would be obvious to one of ordinary skill in the art. It also would be obvious to one of ordinary skill in the art to prepare a basement membrane having DNA content 0.429 ug/mg dry weight or less because both Ollerenshaw and Wolfinbarger teach removing nucleic acid or degrading nucleic acid from a tissue graft and the tissue graft would be substantially devoid of DNA, which would be close to zero and would be obviously less than 0.429 ug/mg dry weight of basement membrane.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to use the liver basement membrane as a cell growth substrate in a variety of forms, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells as taught by Badylak or to implant the basement membrane into a mammalian system as taught by Wolfinbarger with reasonable expectation of success.

8. Claims 11-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak, Stephen, 1998 (WO 98/25637) in view of either Ollerenshaw et al., 2005 (US Patent No. 6,866,686 B2) or Wolfinbarger Jr. et al., 2004 (US Patent No. 6,734,018 B2). Applicants' amendment filed 11-26-08 necessitates this new ground of rejection.

Claims 11-15, 17, 18 and 20 are directed to a purified liver basement membrane graft composition comprising basement membrane of warm-blooded vertebrate liver tissue, wherein

the purified liver basement membrane is substantially devoid of DNA, and wherein the liver basement membrane could be fluidized, in gel form, or in powder form, and a liver tissue derived composition for supporting the growth of a cell population, said composition comprising said liver basement membrane composition and is devoid of source liver tissue endogenous cells, or said composition comprising culture-ware coated with a matrix comprising said liver basement membrane composition. Claims 19 and 21 are directed to a collagenous tissue graft structure comprising decellularized basement membrane wherein the basement membrane is substantially devoid of DNA. Claims 20 and 21 specify the DNA content of the basement membrane is 0.429 ug or DNA or less per mg of dry weight of the basement membrane.

Badylak teaches a tissue graft composition comprising liver basement membrane prepared by removing the cellular components from liver tissue by treating the liver tissue with a solution comprising an enzyme, such as trypsin or pepsin, and a calcium chelating agent or chaotropic agent such as a mild detergent Triton 100, or with a solution comprising only the chelating agent or chaotropic agent (e.g. abstract, p. 3-4). The liver tissue slice can be suspended in an agitated solution containing protease, optionally containing a chaotropic agent or a calcium chealating agent in an amount effective to optimize release and separation of cells from the basement membrane without substantial degradation of the membrane matrix (e.g. p. 4). Badylak further teaches that the liver basement membrane can be fluidized or in powder form (e.g. p. 4-5, 16), cell growth substrate are formed from fluidized forms of liver basement membrane and the fluidized tissue can be gelled to form solid or semi-solid matrix (e.g. p. 11, second paragraph), and the cell growth substrate can be combined with nutrients, such as minerals, amino acids, sugars, peptides, proteins, glycoproteins that facilitate cellular

proliferation and growth factors (e.g. p. 11, third paragraph). Badylak also teaches that "fluidized forms of liver basement membrane can be used to coat culture-ware with a matrix comprising liver basement membrane devoid of source liver tissue endogenous cells. Thus, liver basement membrane can be used as a cell growth substrate in a variety of froms, including a sheet-like configuration, as a gel matrix, as an additive for art-recognized cell/tissue culture media, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells" (e.g. p. 10, 2nd paragraph).

Badylack does not specifically teach the basement membrane is substantially devoid of DNA or the DNA content is 0.429 ug/mg dry weight or less.

Ollerenshaw teaches a tissue graft produced by disinfecting a human or animal ureter tissue, decellularizing the disinfected tissue with an aqueous hypotonic buffer that lyses cells to form a tissue matrix and with nuclease to degrade nucleic acid associated with said tissue matrix, and washing said tissue matrix to remove cellular or extracellular debris to as to produce tissue graft (e.g. column 10, claim 1).

Wolfinbarger teaches a process for the production of commercializable quantities of acellular soft tissue grafts for implantation into mammalian system by removing the cellular populations, cellular remnants, nucleic acids, and small molecular weight proteins, lipids, and polysaccharides forming an acellular nonsoluble matrix. The acellular tissue can be implanted into a mammalian system (e.g. bridging column 2 and 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to prepare a tissue graft structure comprising decellularized basement membrane substantially devoid of DNA because Badylak teaches a tissue graft composition comprising

liver basement membrane prepared by removing the cellular components from liver tissue, and both Ollerenshaw and Wolfinbarger teach preparation of acellular tissue graft by removing cellular populations, and removing nucleic acid or degrading nucleic acid. A basement membrane is a type of tissue graft and removing or degrading nucleic acid in a tissue graft would substantially devoid of DNA in the tissue graft and would be obvious to one of ordinary skill in the art. It also would be obvious to one of ordinary skill in the art to prepare a basement membrane having DNA content 0.429 ug/mg dry weight or less because both Ollerenshaw and Wolfinbarger teach removing nucleic acid or degrading nucleic acid from a tissue graft and the tissue graft would be substantially devoid of DNA, which would be close to zero and would be obviously less than 0.429 ug/mg dry weight of basement membrane.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to use the liver basement membrane as a cell growth substrate in a variety of forms, or as coating for culture-ware to provide a more physiologically relevant substrate that support and enhances the proliferation of cells as taught by Badylak or to implant the basement membrane into a mammalian system as taught by Wolfinbarger with reasonable expectation of success.

Conclusion

No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.
/Shin-Lin Chen/
Primary Examiner, Art Unit 163